Maryland
DEPARTMENT OF HEALTH

# Prolia (Denosumab)

Prolia will be considered for coverage when all of the criteria below are met, confirmed with supporting medical documentation.

## I. Criteria for Initial Approval

- Indicated for the treatment of adult men and postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; and have failed or are intolerant to other available osteoporosis therapy. **All of the following criteria must be met:**
    - Documentation of an osteoporotic fracture or dual-energy x-ray absorptiometry (DEXA) Scan scoring consistent with osteoporosis.
    - Treatment failure or a contraindication with bisphosphonate therapy (i.e. Alendronate, Etidronate, Ibandronate, Risedronate).
    - Patient has been instructed to receive at a minimum both calcium 1000 mg and vitamin D 400 IU daily.
    - Not currently pregnant.
    - Does not have uncorrected hypocalcemia.
- Indicated for the treatment of glucocorticoid-induced osteoporosis in adult men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. **All of the following criteria must be met:**
    - Documentation of an osteoporotic fracture or dual-energy x-ray absorptiometry (DEXA) Scan scoring consistent with osteoporosis.
    - Treatment failure or a contraindication with bisphosphonate therapy (i.e. alendronate, Etidronate, Ibandronate, Risedronate).
    - Patient has been instructed to receive at a minimum both calcium 1000 mg and vitamin D 400 IU daily.
    - Not currently pregnant.

- Providers initially screens and monitors for hypocalcemia during the course of treatment.

- Indicated as a treatment to increase bone mass in adult men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. **All of the following criteria need to be met:**
  - The patient has a diagnosis of non-metastatic prostate cancer.
  - Documentation of an osteoporotic fracture or dual-energy x-ray absorptiometry (DEXA) Scan scoring consistent with osteoporosis.
  - Patient is receiving an Androgen Deprivation Therapy (leuprolide, Goserelin, Triptorelin, Histrelin, Degarelix, Abiraterone, Flutamide, Bicalutamide, Nilutamide, Ketoconazole, Enzalutamide).
  - Providers initially screens and monitors for hypocalcemia during the course of treatment.

- Indicated as a treatment to increase bone mass in adult women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. **All of the following criteria need to be met:**
  - The patient has a diagnosis of breast cancer.
  - Documentation of an osteoporotic fracture or dual-energy x-ray absorptiometry (DEXA) Scan scoring consistent with osteoporosis.
  - The patient is receiving an Aromatase Inhibitor Therapy (Anastrozole, Exemestane, Letrozole)
  - Providers initially screens and monitors for hypocalcemia during the course of treatment.
  - Patients cannot also be taking Xgeva.

## II. Criteria for Continuation of Therapy

**All of the criteria for initial therapy (in Section I.) must be met; <u>AND</u>**

- The provider attests to a positive clinical response.

## III. Dosing/Administration

Prolia must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen.

- All patients should be instructed to receive Calcium 1000mg daily and Vitamin D 400IU daily.

## IV. Length of Authorization For initial therapy

Prolia will be authorized for 6 months when criteria are met. Continuing therapy with Prolia will be authorized for 12 months.

## V. Billing Code/Information

HCPCS Code: J0897 – Injection, denosumab, (60mg - prefilled syringe- 60 Unit Dose) 1 mg = 1 billable unit.

*Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.*

**Approved by MDH Clinical Criteria Committee: 7/28/2020**
**Last Reviewed Date:**